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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1610.1US01	6766

27367 7590 03/19/2007
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900 SECOND AVENUE SOUTH
MINNEAPOLIS, MN 55402-3319

EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

MAIL DATE	DELIVERY MODE
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03/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/475,721	Applicant(s) REIMINK ET AL.	
	Examiner Sow-Fun Hon	Art Unit 1772	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: _____.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attachment to advisory action.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
 13. ☒ Other: Attachment to advisory action.


RENA DYE
SUPERVISORY PATENT EXAMINER

Response to Request for Reconsideration

1. The request for reconsideration filed 02/15/07 has been fully considered and deemed unpersuasive for the reasons set forth below.
2. Applicant argues that a dipping process places a layer having a substantially uniform thickness onto a metal substrate that conforms to the general shape of the substrate, such that a polymer coating of substantially uniform thickness does not provide a structure that is shaped differently from the structure of the substrate as claimed. Applicant further argues that the outer surface of the polymer has the same configuration as the outer surface of the metal substrate, since it is clearly shown that the metal substrate is in the form of a cupped disc and that the polymeric material follows the form of the metal substrate.

Applicant is respectfully apprised that the embodiment of the composite structure of Reul in Fig. 3, shown below, is a medical device (prosthetic heart valve, column 6, line 29) comprising a composite 1 (valve member 1, column 5, line 41, Fig. 3) wherein the encapsulating polymer 14, shaded with \ (blood compatible synthetic material 14, column 5, lines 41-44), provides a structure that defines the form of the device, which is indeed shaped differently from the inorganic substrate 12, shaded with the reverse hatch // (metal substrate 12, column 5, lines 45-47), as defined by Applicant.

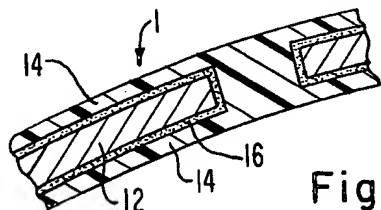


Fig. 3

Applicant teaches that when the polymer member smoothes edges and fills in spaces, it modifies the details of the substrate (specification, page 19, lines 27-29), hence defining the shape of the composite. In addition, Reul teaches that the composite 1 has the shape of a dish (form, valve member 1, column 5, lines 8-10), and that the hinge flap is formed in one piece with the valve member, consisting of the same polymer with which the valve member is encapsulated (column 4, lines 39-45), forming a composite structure that is different from the shape of the inorganic substrate 12. Applicant teaches that additional structure that does not result from simple application of a polymer material over the surface, note the adjective "additional", include barbs and anchors (specification, page 19, line 34, page 20, lines 1-4). Reul's hinge qualifies as an anchor. Applicant needs to better define the structure of the inorganic substrate and the structure of the composite in order to distinguish them over the inorganic substrate and composite of Reul.

3. Applicant argues that Reul does not disclose that the heart valve flexes as it has a substantially different structure than a natural heart valve and opens and closes in a substantially different manner than a natural heart valve.

Applicant is respectfully apprised that Reul discloses that the composite is very thin (less than 0.3 – 0.4 mm, column 3, lines 40-42), such that, by virtue of its composition, which is a thin metal foil substrate and a flexible blood compatible synthetic material body (thin metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45), it is indeed flexible, as defined

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by Applicant. Applicant teaches that a flexible component can include a thin metal foil or the like as the substrate with a flexible polymer material (specification, page 15, lines 25-30).

4. Applicant argues that in a natural heart, each of the leaflets must flex in order to open and close the valve, whereas the valve of Reul does not have the structure of a natural heart valve, having a cup-shaped disc configuration that is hingedly attached to a vessel wall at one end, wherein the flexing of this cup-shaped valve would reduce the response time of the valve and hinder its performance.

Applicant is respectfully apprised that it is unclear to the Office why the reduction of the response time of the valve would hinder its performance. Reul teaches that the valve can react almost instantaneously to the quickly changing pressure gradients inside the heart chamber and thus resembles the natural valve more closely than any other existing artificial heart valve [at the time of the invention] (column 3, lines 40-50). Thus Reul teaches that the reduction of response time of the valve is a performance attribute, and not a hindrance.

7. Applicant argues that if the valve of Reul flexes, then the response of the pressure gradient decreases in direct contrast to the disclosure of Reul. Applicant further argues that a flexing member would consume energy that would normally be used to move the cupped valve about its hinge, which is in direct contradiction to the disclosure of the Reul patent.

Applicant is respectfully reminded that first of all, that as discussed above, the composite member disclosed by Reul does flex, as defined by Applicant's specification.

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Secondly, Applicant has not demonstrated that the flexibility of Reul's valve, as defined by Applicant, would present a direct contradiction to the function of Reul's valve as disclosed by Reul. Note the qualifier "as defined by Applicant".

8. Applicant argues that the examiner has not provided evidence that the cup-shaped valve as disclosed in the Reul patent must inherently flex, and that rather, in contrast, the Reul patent discloses that it would be disadvantageous for the valve to have flexing capabilities.

Applicant is respectfully reminded that Applicant teaches that a flexible component can include a thin metal foil or the like as the substrate with a flexible polymer material (specification, page 15, lines 25-30). Reul discloses that the composite is very thin (less than 0.3 – 0.4 mm, column 3, lines 40-42), such that, by virtue of its composition, which is a thin metal foil substrate and a flexible blood compatible synthetic material body (thin metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45), it is indeed flexible, as defined by Applicant. Applicant has not provided evidence that it would be disadvantageous for the valve to have flexing capabilities in terms of the flexibility of the valve as defined by Applicant. Note the qualifier "as defined by Applicant".

9. Applicant's arguments against the secondary references are directed against the validity of the primary reference Reul, which are addressed above.

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Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

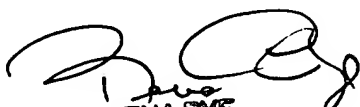
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon.

Sow-Fun Hon

03/07/07


RENA DYE
SUPERVISORY PATENT EXAMINER
AU 1774